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| FORM PTO-1390<br>(REV. 1-98)  |  | U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE | ATTORNEY'S DOCKET NUMBER<br><b>45669/304008</b>                      |
| <b>TRANSMITTAL LETTER TO THE UNITED STATES<br/>DESIGNATED/ELECTED OFFICE (DO/EO/US)<br/>CONCERNING A FILING UNDER 35 U.S.C. 371</b>   |  |   | U.S. APPLICATION NO. (If known, see 37 CFR 1.5)<br><b>10/505,291</b> |
| INTERNATIONAL APPLICATION NO.<br><b>PCT/IB03/00500</b>  | INTERNATIONAL FILING DATE<br><b>14 February 2003</b> | PRIORITY DATE CLAIMED<br><b>19 February 2002</b>        |  |
| TITLE OF INVENTION<br><b>Pharmaceutical Combinations of Cox-2 Inhibitors and Opiates</b>  |  |   |  |
| APPLICANT(S) FOR DO/EO/US<br><b>Michael Christian Norris</b>  |  |   |  |
| Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:   |  |   |  |
| <p>1. <input type="checkbox"/> This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.</p> <p>2. <input checked="" type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.</p> <p>3. <input type="checkbox"/> This express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicates below.</p> <p>4. <input type="checkbox"/> The US has been elected (Article 31).</p> <p>5. <input type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2))</p> <p style="margin-left: 20px;">a. <input type="checkbox"/> is attached hereto (required only if not transmitted by the International Bureau).</p> <p style="margin-left: 20px;">b. <input type="checkbox"/> has been transmitted by the International Bureau.</p> <p style="margin-left: 20px;">c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</p> <p>6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).</p> <p style="margin-left: 20px;">a. <input type="checkbox"/> is attached hereto.</p> <p style="margin-left: 20px;">b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).</p> <p>7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))</p> <p style="margin-left: 20px;">a. <input type="checkbox"/> are attached hereto (required only if not transmitted by the International Bureau).</p> <p style="margin-left: 20px;">b. <input type="checkbox"/> have been transmitted by the International Bureau.</p> <p style="margin-left: 20px;">c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</p> <p style="margin-left: 20px;">d. <input type="checkbox"/> have not been made and will not be made.</p> <p>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</p> <p>9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</p> <p>10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</p> <p>Items 11 to 20 below concern document(s) or information included:</p> <p>11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.197 and 1.98</p> <p>12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</p> <p>13. <input type="checkbox"/> A FIRST preliminary amendment.</p> <p>14. <input type="checkbox"/> An Application Data Sheet under 37 CFR 1.76.</p> <p>15. <input type="checkbox"/> A substitute specification.</p> <p>16. <input type="checkbox"/> A power of attorney and/or change of address letter.</p> <p>17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1-821-1.825.</p> <p>18. <input type="checkbox"/> A second copy of the published international application under 35 U.S.C. 154(d)(4).</p> <p>19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).</p> <p>20. <input checked="" type="checkbox"/> Other items or information:</p> |  |   |  |
| Express Mail Label Number EV 041632347 US   |  |   |  |
| Date of Deposit: 23 December 2004   |  |   |  |

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| <p>21. <input type="checkbox"/> The following fees are submitted</p> <p><b>BASIC NATIONAL FEE (37 CFR 1.492(a)(1)-(5)):</b></p> <p>Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2) paid to USPTO and International Search Report not prepared by the EPO or JPO <span style="float: right;">\$1080.00</span></p> <p>International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO <span style="float: right;">\$920.00</span></p> <p>International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2) paid to USPTO <span style="float: right;">\$770.00</span></p> <p>International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) <span style="float: right;">\$730.00</span></p> <p>International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) <span style="float: right;">\$100.00</span></p> <p style="text-align: right;"><b>ENTER APPROPRIATE BASIC FEE AMOUNT =</b> \$</p> |              |              |            | <p><b>CALCULATIONS PTO USE ONLY</b></p> |    |
| <p>Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(e)).</p>   |              |              |            | \$                                      |    |
| CLAIMS  | NUMBER FILED | NUMBER EXTRA | RATE       |   |    |
| Total claims  | 41 - 20 =    | 21           | X \$18.00  | \$                                      |    |
| Independent claims  | 4 - 3 =      | 1            | X \$86.00  | \$                                      |    |
| MULTIPLE DEPENDENT CLAIM(S) (if applicable)   |              |              | + \$290.00 | \$ .00                                  |    |
| <b>TOTAL OF ABOVE CALCULATIONS =</b>  |              |              |            | \$                                      |    |
| <input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.  |              |              |            | \$ .00                                  |    |
| <b>SUBTOTAL =</b>   |              |              |            | \$ .00                                  |    |
| Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)).   |              |              |            | \$ .00                                  |    |
| <b>TOTAL NATIONAL FEE =</b>   |              |              |            | \$ .00                                  |    |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40 per property +   |              |              |            | \$ .00                                  |    |
| <b>TOTAL FEES ENCLOSED =</b>  |              |              |            | \$                                      |    |
|   |              |              |            | Amount to be refunded:                  | \$ |
|   |              |              |            | charged:                                | \$ |

  

a. ☐ A check in the amount of \$\_\_\_\_\_ to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account No. 11-0855 in the amount of \$\_\_\_\_\_ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 11-0855. A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b) must be filed and granted to restore the application to pending status.

  

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| CORRESPONDENCE ADDRESS:           | CUSTOMER NUMBER: <b>23370</b> | <br>SIGNATURE                 |
| John S. Pratt, Esq.               |                               | Name: John K. McDonald, Ph.D. |
| KILPATRICK STOCKTON LLP           |                               | Registration No. 42,860       |
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| Atlanta, Georgia 30309-4530       |                               |                               |